FEB 2 4 2010

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: August 4, 2009

Submitter: GE Healthcare (GE Medical Systems *Information Technologies*)
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Wauwatosa, WI 53226

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Device: Trade Name: 12SL ECG Analysis Program

Common/Usual Name: ECG Analysis Program

Classification Names: Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms)

Product Code: 74MHX 21CFR 870.1025

Predicate Device(s): K060833; 12SL EGG Analysis Program with Right Ventricular Analysis

Device Description: The 12SL ECG Analysis Program is a software algorithm only.

Intended Use: The 12SL ECG Analysis Program assists the physician in measuring and interpreting resting 12-lead ECGs for rhythm and contour information by providing an initial automated interpretation. Interpretation by the product is then confirmed, edited, or deleted by the physician. The analysis program is intended for use in the general population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities. The analysis program is intended for use in hospitals, outpatient clinics, emergency departments, and out-of hospital sites such as ambulances and patients' homes.
ACS Tool option is intended for adult patient population who are suspected clinically to have acute coronary syndrome.

Technology: The 12SL ECG Analysis Program employs the same functional scientific technology as its predicate device.

Determination of Substantial Equivalence: Summary of Non-Clinical Tests:

There are no recognized consensus standards applicable to the 12SL ECG Analysis System algorithm. The 12SL ECG Analysis Program and its applications comply with the Guidances and/or Special Controls as detailed in Section 9 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Requirements Reviews
- Risk Analysis
- Software Verification and Validation
- Performance testing

Summary of Clinical Tests:

The subject of this premarket submission, 12SL ECG Analysis Program, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the 12SL ECG Analysis Program to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB 24 2010

GE Medical Systems Information Technologies
c/o Joseph Lucas, Regulatory Leader
9900 Innovation Drive
Wauwatosa, WI 53226

Re: K092369
Trade/Device Name: 12SL ECG Analysis Program
Regulation Number: 21 CFR 870.1025
Regulation Name: Monitor, Physiological, Patient (With Arrhythmia Detection or Alarms)
Regulatory Class: Class II (special controls)
Product Code: MHX
Dated: February 15, 2010
Received: February 18, 2010

Dear Mr. Lucas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

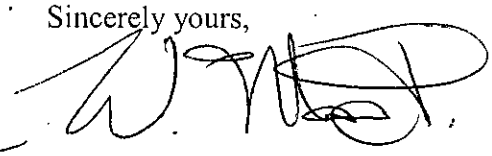
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K092369

Device Name: 12SL ECG Analysis Program

Indications for Use:

The 12SL ECG Analysis Program assists the physician in measuring and interpreting resting 12-lead ECGs for rhythm and contour information by providing an initial automated interpretation. Interpretation by the product is then confirmed, edited, or deleted by the physician. The analysis program is intended for use in the general population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities. The analysis program is intended for use in hospitals, outpatient clinics, emergency departments, and out-of hospital sites such as ambulances and patients' homes.

ACS Tool option is intended for adult patient population who are suspected clinically to have acute coronary syndrome.

Prescription Use_X___ AND/OR Over-The-Counter Use__
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092369